K123055 (pg 1/5)

Summary of Safety and Effectiveness
Plate and Screw Systems Instruments
Smith & Nephew, Inc.

JAN 25 2013

Contact Person and Address
Bradley Heil
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Memphis, Tennessee 38016
T (901) 399-6339

Date of Summary: September 27, 2012

Name of Device: Plate and Screw Instruments
Common Name: Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:

21 CFR 888.3010 – Bone fixation cerclage
21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener

Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices:

Pelvic Radius Plate (K936233)
Titanium Classic Compression Hip Screw System (K952697)
Compression Cerclage Gundolf CCF-GF (K973098)
Smith & Nephew Bone Plate System (Bone Plates and Screws & Accessories) (K993106) PLUS Cancellous Bone Screws (K011719)
Smith & Nephew Locking Bone Plate System (Locking Bone Plates and Screws) (K033669)
HA Coated Lag Screw (K050849)
PERI-LOC Locking Bone Plates and Locking Bone Screws for the Upper Extremity (K051735)
Smith & Nephew 6.5MM and 8.0MM Cannulated Screws (K060736)
PERI-LOC Periarticular Locked Plating System for the Upper Extremity (K061352)
PERI-LOC Periarticular Locked Plating System (K071563)
PERI-LOC Periarticular Locked Plating System - Proximal Femoral Plates/Screws, Cable Accessories (K072818)
INTERTAN CHS Locking Plate System Proximal Femoral Plates/Screw (K080434)
PERI-LOC Periarticular Locked Plating System Volar Distal Radius Locking Plate for the Upper Extremity (K081106)
PERI-LOC Periarticular Locked Plating System Hexalobular Bone Screws (K082516)
PERI-LOC Bone Plating and Screw System (K083032)
INTERTAN CHS Limited Collapse Set Screw (K090656)
Smith & Nephew VLP Foot Plating, Screw System & Accessories (K090675)
PERI-LOC Periarticular Locked Plating System (K092015)
PERI-LOC Locking Hole Inserts and Cable Accessories (K100325)

Summary of Safety and Effectiveness
Plate and Screw Systems Instruments
Smith & Nephew, Inc.

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Plate and Screw Systems Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Plates and Screws and their cleared Indications for Use. Smith & Nephew Plate and Screw Systems Instruments can be organized into instrument families which are categorized as follows: Templates, Reamers, Handles, Bases, Pins, Taps, Drill Guides, Insertion or Removal, and Other Guides.

Intended Use

Smith & Nephew Plate and Screw Systems Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Plate and Screw Systems and their cleared Indications for Use.

PERI-LOC Locking Bone Plates, Locking Hole Inserts and Cable Accessories

Smith & Nephew PERI-LOC Locking Bone Plates, Locking Hole Inserts and Cable Accessories Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Periarticular Locked Plating Systems and their cleared indications for use.

The PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. The PERI-LOC Proximal Femur Locking Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories are indicated for:

- fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with the medial cortex instability
- proximal femur fractures combined with ipsilateral shaft fractures
- pathological fractures of the proximal femur including metastatic fractures
- proximal femur osteotomies
- fixation of fractures in osteopenic bone
- fixation of nonunions and malunions
- basi/transcervical femoral neck fractures
- subcapital femoral neck fractures
- subtrochanteric femur fractures.

In addition, the PERI-LOC Periarticular Locked Plating System including Locking Hole Inserts and Cable Accessories can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bone plates and screws are indicated for:

- fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Smith & Nephew VLP FOOT Plating System, Screw System and Accessories

Smith & Nephew VLP FOOT Plating System, Screw System and Accessories Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew VLP FOOT Plating System and Screw Systems and their cleared indications for use.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP Plating System is indicated for:

- the treatment of fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew Screw Systems, containing 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws, are indicated for:

- fixation of interarticular and extra-articular fractures and non-unions of small bones and small bone fragments;
- arthrodesis of small joints;
- bunionectomies and osteotomies;
- scraphold and other carpal bones;
- metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The Smith & Nephew 2.0mm QFX Screw is indicated for:

- osteotomies of the lesser metatarsals, such as Weil osteotomies, osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.

Smith & Nephew Accessories, such as pins and wires, are indicated for:

- pelvic, small and long bone fracture fixation.

Smith & Nephew InterTAN CHS Limited Collapse Set Screw

Smith & Nephew InterTAN CHS Limited Collapse Set Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew InterTAN CHS Limited Collapse Set Screw Systems and their cleared indications for use.

InterTAN CHS Limited Collapse Set Screw is indicated for:

K123055 (pg 4/5)

- Intracapsular fractures of the proximal femur (For certain high subcapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head).
- Intertrochanteric fractures.
- Stable and unstable fractuers of the proximal femur in which medial cortex stability can be restored.
- Hip osteotomy

PERI-LOC Periarticular Locked Plating System- VLP Locking Bone Plates and Locking/Non-Locking Bone Screws

Smith & Nephew VLP Locking Bone Plates and Locking/Non-Locking Bone Screws Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PERI-LOC Periarticular Locked Plating Systems and their cleared indications for use.

PERI-LOC Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC contoured VLP Plates and Screws are indicated for:

- partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia and for fracture fixation of the fibula

PERI-LOC VLP One-Third Tubular Locking Plates are indicated for:

- fixation of fractures, non-unions, and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws

Smith & Nephew 6.5mm and 8.0mm Cannulated Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew 6.5mm and 8.0mm Cannulated Screw Systems and their cleared indications for use.

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws are indicated for:

- fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones;
- treatment of the calcaneal
- hip arthrodesis
- provisional bone fixation.

Smith & Nephew Bone Plate System

Smith & Nephew Bone Plate System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Bone Plate Systems and their cleared indications for use.

Smith & Nephew Bone Plates, Bone Screws, and Accessories are indicated for:

- pelvic fracture fixation
- small bone fracture fixation
- long bone fracture fixation.

Titanium Classic Compression Hip Screw System

Smith & Nephew Titanium Classic Compression Hip Screw System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Titanium Classic Compression Hip Screw Systems and their cleared indications for use.

The Titanium Classic Compression Hip Screw System is indicated for:

- Pelvic Radius Plate- general fractures of the pelvis and acetabulum
- Tibial Plateau Plate- fractures of the proximal tibia with or without diaphyseal involvement
- One Third Tubular Plate- fractures of the fibula, lateral malleolus, metacarpals, metatarsals, olecranon, and distal ulna
- Small Auto-Compression Plate- fracture fixation of metatarsals, metacarpals, radius, and ulna
- Titanium Cortical Bone Screw- small and long bone fracture fixation

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith & Nephew Plate and Screw Systems Instruments are similar in design and function to competing plate and screw surgical instrumentation on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated
% Mr. Bradley Heil
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Letter dated: January 25, 2013

Re: K123055
Trade/Device Name: PERI-LOC Locking Bone Plates, Locking Hole Inserts and Cable Accessories
Smith & Nephew VLP FOOT Plating System, Screw System and Accessories
Smith & Nephew InterTAN CHS Limited Collapse Set Screw
PERI-LOC Periarticular Locked Plating System – VLP Locking Bone Plates and Locking/Non-Locking Bone Screws
Smith & Nephew 6.5mm and 8.0mm Cannulated Screws
Smith & Nephew Bone Plate System
Titanium Classic Compression Hip Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HTY, HWC, JDO
Dated: September 27, 2012
Received: November 2, 2012

Dear Mr. Heil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123055 (pg 1/7)

Device Name: PERI-LOC Locking Bone Plates, Locking Hole Inserts and Cable Accessories
Indications for Use:

Smith & Nephew PERI-LOC Locking Bone Plates, Locking Hole Inserts and Cable Accessories Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Periarticular Locked Plating Systems and their cleared indications for use.

The PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. The PERI-LOC Proximal Femur Locking Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories are indicated for:

- fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with the medial cortex instability
- proximal femur fractures combined with ipsilateral shaft fractures
- pathological fractures of the proximal femur including metastatic fractures
- proximal femur osteotomies
- fixation of fractures in osteopenic bone
- fixation of nonunions and malunions
- basi/transcervical femoral neck fractures
- subcapital femoral neck fractures
- subtrochanteric femur fractures.

In addition, the PERI-LOC Periarticular Locked Plating System including Locking Hole Inserts and Cable Accessories can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bone plates and screws are indicated for:

- fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:54:30 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055 (pg 217)

Device Name: Smith & Nephew VLP FOOT Plating System, Screw System and Accessories
Indications for Use:

Smith & Nephew VLP FOOT Plating System, Screw System and Accessories Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew VLP FOOT Plating System and Screw Systems and their cleared indications for use.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP Plating System is indicated for:

- the treatment of fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew Screw Systems, containing 2.5mm, 3.0mm Cannulated and 3.0mm Headless Compression Screws, are indicated for:

- fixation of interarticular and extra-articular fractures and non-unions of small bones and small bone fragments;
- arthrodesis of small joints;
- bunionectomies and osteotomies;
- scraphold and other carpal bones;
- metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The Smith & Nephew 2.0mm QFX Screw is indicated for:

- osteotomies of the lesser metatarsals, such as Weil osteotomies, osteotomies, fusions and fractures of the phalanges, metacarpals and carpals of the hand.

Smith & Nephew Accessories, such as pins and wires, are indicated for:

- pelvic, small and long bone fracture fixation.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:54:09 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055 (pg 3/7)

Device Name: Smith & Nephew InterTAN CHS Limited Collapse Set Screw
Indications for Use:

Smith & Nephew InterTAN CHS Limited Collapse Set Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew InterTAN CHS Limited Collapse Set Screw Systems and their cleared indications for use.

InterTAN CHS Limited Collapse Set Screw is indicated for:

- Intracapsular fractures of the proximal femur (For certain high subcapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head).
- Intertrochanteric fractures.
- Stable and unstable fractuers of the proximal femur in which medial cortex stability can be restored.
- Hip osteotomy

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:53:33 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055 (pg 4 | 7)

Device Name: PERI-LOC Periarticular Locked Plating System- VLP Locking Bone Plates and Locking/Non-Locking Bone Screws

Indications for Use:

Smith & Nephew VLP Locking Bone Plates and Locking/Non-Locking Bone Screws Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PERI-LOC Periarticular Locked Plating Systems and their cleared indications for use.

PERI-LOC Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC contoured VLP Plates and Screws are indicated for:

- partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia and for fracture fixation of the fibula

PERI-LOC VLP One-Third Tubular Locking Plates are indicated for:

- fixation of fractures, non-unions, and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:53:09 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055(pg 5/7)

Device Name: Smith & Nephew 6.5mm and 8.0mm Cannulated Screws
Indications for Use:

Smith & Nephew 6.5mm and 8.0mm Cannulated Screw Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew 6.5mm and 8.0mm Cannulated Screw Systems and their cleared indications for use.

Smith & Nephew 6.5mm and 8.0mm Cannulated Screws are indicated for:

- fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones;
- treatment of the calcaneal
- hip arthrodesis
- provisional bone fixation.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:52:48 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055 (pg 6/7)

Device Name: Smith & Nephew Bone Plate System
Indications for Use:

Smith & Nephew Bone Plate System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Bone Plate Systems and their cleared indications for use.

Smith & Nephew Bone Plates, Bone Screws, and Accessories are indicated for:

- pelvic fracture fixation
- small bone fracture fixation
- long bone fracture fixation.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:52:28 -05'00'

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K123055 (pg 7/7)

Device Name: Titanium Classic Compression Hip Screw System
Indications for Use:

Smith & Nephew Titanium Classic Compression Hip Screw System Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Titanium Classic Compression Hip Screw Systems and their cleared indications for use.

The Titanium Classic Compression Hip Screw System is indicated for:

- Pelvic Radius Plate- general fractures of the pelvis and acetabulum
- Tibial Plateau Plate- fractures of the proximal tibia with or without diaphyseal involvement
- One Third Tubular Plate- fractures of the fibula, lateral malleolus, metacarpals, metatarsals, olecranon, and distal ulna
- Small Auto-Compression Plate- fracture fixation of metatarsals, metacarpals, radius, and ulna
- Titanium Cortical Bone Screw- small and long bone fracture fixation

Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X		(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens
2013.01.23 17:51:59 -05'00'

Division of Orthopedic Devices